PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: FUJIMOTO, AKIHIDE ET AL.	EXAMINER: STEVEN C. POHNERT
APPLICATION NO.: 10/801,956	ART UNIT: 1634
FILED: MARCH 15, 2004	CONF. NO: 2356
FOR: **LOSS OF HETEROZYGOSITY OF THE DNA MARKERS IN THE 12q22-23 REGION**	

DECLARATION OF INVENTOR DAVE S.B. HOON UNDER 37 CFR 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Dave S.B. Hoon, declare as follows:

1. I am co-inventor of U.S. Patent Application Serial No. 10/801,956 ('956 Application). I am a full member of the John Wayne Institute for Cancer Treatment and Research and the Director of the Department of Molecular Oncology. I have been involved in the treatment and study of cancer for over 20 years. Presently, I am involved in molecular and surgical oncology translational research. My work involves the development of molecular/genetic surrogate biomarkers for assessment of cancer treatment responses, diagnosis, prognosis and staging of specific solid tumor cancers. One particular focus of my work is the assessment of molecular/genetic biomarkers such as circulating tumor cells and

circulating DNA in body fluids. Attached hereto is a copy of my current curriculum vitae.

2. I have reviewed the Office Action dated April 26, 2010 of the '956 Application, and in particular focused on the obviousness rejections of the pending claims based, in part, on Soengas et al. (Nature, 2001, volume 409, pages 207-211) which is referred to in this declaration as the "Soengas reference" or "Soengas." I have also reviewed the Soengas reference.

3. In accordance with the official guidelines by the American Joint Committee on Cancer (AJCC), Stage III melanoma is diagnosed by the presence of melanoma tumors that have spread to the regional lymph nodes or have developed in transit metastasis or satellites. According to the AJCC guidelines, Stage IV melanoma is diagnosed by melanoma tumors that have spread beyond the regional lymph nodes to distant sites in the body. The most common sites of metastasis are to the vital organs such as the brain, lungs, and abdominal organs and soft tissues. In contrast, Stage I and Stage II melanomas are not associated with metastasis.

4. The Soengas reference, in part, analyzes Apaf-1 expression and loss of heterozygosity (LOH) at the Apaf-1 locus in metastatic melanoma samples and the Apaf-1 expression in primary melanoma tumors (pp. 207-208), and Apaf-1 expression and Apaf-1 mutations in cell lines derived from metastatic melanomas (p. 208). In assessing LOH at the Apaf-1 locus, Soengas examined the LOH at microsatellite DNA markers D12S1657, D12S393, D12S1706, and D12S346. The

LOH at the markers was then associated with the expression or lack of expression of Apaf-1 by measuring mRNA (p. 207 Fig.1 (b)(c)).

5. Notably, Soengas does not teach or direct one of ordinary skill in the art to measure the LOH at microsatellite DNA markers D12S327, D12S1657, D12S393, D12S1706, and D12S346 from acellular DNA derived from the blood of a metastatic melanoma patient to predict the probability of survival, prognosis, or cancer therapy efficacy. One of ordinary skill in the art could not reasonably predict or assume that LOH of microsatellite DNA markers in a melanoma metastatic tumor would be the same in the acellular DNA derived from a metastatic melanoma patient's blood. For example, in Fujiwara et al., (Cancer Research, 1999, volume 59, pages 1567-1571) ("Fujiwara"), we demonstrated, that while LOH of microsatellite markers can be determined from acellular DNA, the LOH of microsatellite markers from informative metastatic melanoma tumors and informative acellular DNA from metastatic melanoma patients was not identical or predictable.

6. One of ordinary skill in the art would not be enabled, let alone expect to predict the probability of survival, prognosis, or cancer therapy efficacy based upon the LOH data in Soengas because as shown in Fujiwara, merely detecting LOH of a microsatellite marker does not predict prognosis, outcome or efficacy of treatment.

7. The method of using acellular DNA derived from patient blood to detect LOH provides a significant clinical advantage over LOH detection using tumor tissue because the method is non-invasive. This methodology provides a

particularly significant advantage to Stage IV patients as they often have inoperable tumors (e.g. brain tumors) that pose significant risk for biopsy.

I hereby declare under penalty of perjury under the laws of the United States of America that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dave S.B. Hoon

12/8/2010
Date

CURRICULUM VITAE

Name: ***DAVE S.B. HOON***
Wife: Hiroko
Date of Birth: 4/21/1955
Place of Birth: Victoria, British Columbia, Canada

Positions:
1997-present: Full Member, John Wayne Institute For Cancer Treatment and Research.
Director, Dept. Molecular Oncology.
1991-1996: Associate Member, John Wayne Institute Cancer Treatment and Research.
Director, Dept. Molecular & Cellular Immunology.
1988-1991: Assistant Professor, Division of Surgical Oncology, Department of Surgery,
U. of California Los Angeles School of Medicine, John Wayne Cancer Clinic.
1988-1994: Assistant Clinical Professor, Medical Surgical Section, U. of California Los Angeles
School of Nursing.

Postdoctoral Fellowship - Division of Surgical Oncology, Department of Surgery,
UCLA School of Medicine, 1983-86
Human tumor immunology
Research Oncologist - Division of Surgical Oncology, Department of Surgery,
UCLA School of Medicine, 1986-88.

Sabbaticals:
1994: Osaka Institute Molecular & Cellular Biology, Division Cellular Genetics,
Osaka University, Japan.

DEGREES
B.Sc. (Functional Biology) 4 year program, U. of Victoria, 1977.
Field of study - zoology
M.Sc. (Pathology) U. of Manitoba, Health Science, 1979.
Field of study - tumor virus cell biology
Ph.D (Microbiology, Immunology) U. of Saskatchewan, 1983.
Field of study - immune response to tumor metastasis

- Member of Canadian Armed Forces (Army Reserves); Commissioned officer, Rank: Captain (1973-1976).
- Member of Royal Canadian Mounted Police (1977-1978).

GRANT AWARDS
- Saskatchewan Health Research Board Scholarship (Ph.D)
- Canadian Cancer Society Fellowship
- Presidential California Cancer Award 1990
- Joseph Drown Foundation Award 1992, 1993, 1994, 1995
- Candle Foundation Award 1992
- NIH, NCI Program Project Surgery Immunology Immunotherapy (Project II Principal Investigator, Director): 1992-1997, Renewal, 1997-2002; Renewal 2002-2009; Renewal Submitted, 2009.

- NIH, NCI Program Project Surgery Immunology Immunotherapy (Molecular Core, Project II Principal Investigator, Director): 2002-2009; Renewal Submitted, 2009.
- NIH Program Project New Approaches to Surgery Oncology (Project II Principal Investigator, Director); 1993-1998; Renewal, 1998-2003; Renewal, 2003-2009; Renewal, 2009-2015.
- NIH Program Project New Approaches to Surgery Oncology (Molecular Core, Principal Investigator, Director); 2003-2009; Renewal, 2009-2015.
- US DOD Army Breast Cancer, 1996-1998, 2001-2003.
- California Breast Cancer Research Program, 1999-2001, 2001-2003, 2003-2007.
- Susan Komen Breast Cancer Foundation 2001-2003, 2004-2006, 2007-2010.
- US DOD Army Prostate Cancer, 2002-2006.
- USA DOD Army Prostate Cancer, 2007-2010.
- NIH NCI R21/R33 2003-2010.
- Avon Breast Research Foundation, 2005-2008
- Novartis Breast Clinical Trials, Biomarker Studies, 2007-2010.
- Adelson Melanoma Foundation (3 projects; PI, Co-PI), 2008-present
- Sysmex Phase III Breast Cancer Clinical Trials, Sentinel Node Molecular Staging, 2008-2009.
- Melanoma Research Alliance Team Program (MGH, Broad Institute, Stanford). Overall Project PI, 2008-2011.
- Abraxis HealthCare Sponsored Research Program PI, 2009-2012.
- Abraxis Phase III Clinical Trials, Biomarker Companion Studies, 2009-
- California Breast Cancer Research, 2010-2012.
- The Dr. Miriam and Sheldon G. Adelson Medical Research Foundation, 2010-2011.

DISTINGUISHED HONORS

- Boerhaave Honorary Professorship and Medal (Surgery Oncology) at Leiden University Medical Center (LUMC), Netherlands, 2010.

Current Research Focus

- Molecular and surgical oncology translational research. Development of molecular/genetic surrogate biomarkers for assessment of cancer treatment responses, diagnosis, prognosis and staging of specific solid tumor cancers. Emphasis on assessment of molecular/genetic biomarkers such as circulating tumor cells and circulating DNA in body fluids. Molecular staging of sentinel lymph node and tumors in melanoma, breast cancer, and colorectal cancer.
- Development of prognostic molecular/genetic biomarker companion studies in phase II and III multicenter clinical trials.
- Monitoring tumor immunotherapy response in patients.

TEACHING

- Laboratory teacher of clinical microbiology for nursing and pharmacy students (1979-1981). U. of Saskatchewan
- Laboratory teacher of basic immunology technique laboratory (1979-1982). U. of Saskatchewan.
- Consultant and assistant for graduate student seminar course, pathology 250A, UCLA, 1984.
- Teacher and supervisor for undergraduates, Biology 199, Microbiology 199 (research program 3rd and 4th yr), UCLA (1992-2004).
- Dean of Honors and Undergraduate programs, College of Letters and Science, UCLA. 1987-1991.
- Supervisor and instructor of UCLA SRP (student research program) for undergraduate science majors; 1988-2008.
- Teaching and advising medical students in surgery/oncology and immunology research series program, UCLA 1986-1991.
- Supervisor and teacher of medical students in UCLA Medical Students Summer Research Program 1985-89.
- Committee Member MSc. Thesis Dissertation: Stephanie Chang, RN, UCLA School of Nursing, Medical Surgical Section. 1990.
- Supervisor of medical student research program: 4th year medical school elective; 1985, 1988-1991.
- Research Program Supervisor/Mentor: Surgery Oncology Fellowship Board Certified Program (Senior and Junior): 1991-2010 (>20 fellows).
- Lecturer in Nursing Oncology 419, post-graduate program, UCLA School of Nursing, 1988-1995.
- Teaching 1st and 2nd year medicine electives: Developed course: Concepts in Vaccines. 1990.
- Teaching: UCLA Extension Course; Self and Non-self; The Human Immune System. 1991.
- Committee Member PhD: T. Nakayama, MD, Dept. Surgery, Osaka U. School of Medicine, Osaka, Japan. 2002.
- Supervisor and mentor, Undergraduate Research Fellows Program Award, Honors Collegium: Andy N. Tran, UCLA 2004; Melanie Wu, UCLA 2005; Terrance Yu, UCLA 2007.
- Supervisor and mentor: NIH Special Emphasis, Clinical Fellow Loans and Basic Research Program Fellowship, 2004-2007; Lori Wilson MD, Joseph Kim MD, Steve Martinez MD, Farin Amersi, MD.
- Mentor Advisor; AACR Mentor Program (New Investigators), AACR Annual Meeting, Anaheim, 2005; AACR Annual Meeting, Los Angeles, 2007; AACR Annual Meeting, San Diego, 2008.
- Committee Member, PhD: Ramin Shayan MBBS, Dept Surgery, University of Melbourne, Victoria, Australia. 2009.
- Committee Member and Supervisor, PhD: Michiel de Maat, MD, Dept of Surgery, Leiden University Medical Center, Leiden, Netherlands 2010.
- Committee Member and Supervisor, PhD: Anneke van Hoesel, Dept of Surgery, Leiden University Medical Center, Leiden, Netherlands 2010.

- Supervisor of laboratory research postdoctoral fellows (MD, MD/PhD, PhD), 1986-2010 (>40 fellows)

SOCIETY MEMBERSHIPS

- American Association of Immunology, American Association Clinical Oncology, American Society Gene Therapy, American Association Clinical Chemistry, American Association of Cancer Research, American Association Human Genetics, Federation of Experimental Biology, U. of Victoria alumni, U. of Manitoba alumni, U. of Saskatchewan alumni, U. of California, Los Angeles Medical alumni.

COMMITTEE MEMBERSHIPS

- Board Member: International Society of Sentinel Node 2000-2010
- Chairman/Organizer: Circulating Nucleic Acids in Plasma/Serum III and Serum Proteomics international meeting 2004, Santa Monica, CA.
- Faculty Board, International SLN Society, 2002-present
- External advisory committee Skin Spore, Wistar Institute U. of Pennsylvania, 2005- 2009.
- External advisory committee Skin Spore, M.D. Anderson, U. of Texas, 2005-present.
- External advisory committee Melanoma Program, Taussig Cancer Center, Cleveland, OH. 2008-present)
- Advisory Board, Omnimmune, 2006-present.
- Global advisory Board, Schering Plough, 2007-present: Treatment Monitoring Biomarkers.
- Advisory Board, Champions Biotechnology, 2007-present.
- Advisory Board, Bristol-Myers Squibb, 2008
- Advisory Board and CSO, OnCirc Biotechnology, 2009-present.
- Chairman/Organizer: 1st Gonda Sarcoma Symposium, Santa Monica, CA, December 2009.

PATENTS

- Issued:
  - Multimarker RT-PCR assays for detection of metastatic melanoma and breast cancer cells (1999).
  - DNA cancer vaccines using HVJ and liposome delivery system(2001)
  - DNA microsatellite serum testing (2002)
  - RNA cancer vaccine using HVJ and liposome delivery system (2002)
  - New tumor associated gene, HOJ-1, chromosome 12 (2003)
  - Diagnostics and therapeutic patents (>20) (2003-present)
  - Licensed 20 patents (diagnostic & therapeutics) to Abraxis Pharmaceutical, 2009.
  - Licensed 3 patents (diagnostic) to OnCirc, 2009.

INSTITUTE ADMINISTRATION

- FDA protocol design, development and validation assays for vaccine product release for patient treatment (CancerVax), 2000-2002.
- Radiation Safety Officer, JWCI: 1992-2010. Radiation Safety Officer, CancerVax, Marina Del Rey: 2000-2002
- Scientific Review Committee JWCI (member) 2003-2010
- Director JWCI Educational Program 2006-2010

JOURNAL REVIEWER

Journals: Amer. J Pathol, Biomedicine, Biotechniques, Breast Cancer Research and Treatment British Journal Cancer, Cancer, Cancer Genes Chromosomes, Cancer Detection & Prevention, Cancer Immunol

Immunother., Cancer Letter, Cancer Res., Cell Death and Differentiation, Clin. Cancer Res., Clin Chem, Cytokine, Hepatology, Int. J. Cancer, J. Immunol., J. Immunol. Meth, J. Immunotherapy, J. Clin. Invest., J. Invest. Dermatology, J. Clin. Oncol., J. Nat.Cancer Inst., Lancet Oncology, Molecular Cancer Research, Molecular Therapy, Melanoma Res., Nature Clinical Oncology Rev, Nature Signaling Gateway Review, Neoplasia, New Engl. J. Med., Oncogene, Oncology, Pigment Res, Proc. Natl. Acad. Sci (USA).

STUDY SECTION AND INSTITUTE COMMITTEE REVIEWER

- Study section *ad hoc* member (Immunology); American Cancer Society, 1991.
- Study section *ad hoc* member (Experimental Immunology); NIH, NCI, 1994.
- Study section *ad hoc* member (Immunology) US Army Breast Cancer Task Force, 1996.
- Study section member NIH-NIAID, Innovation Program in HIV Vaccine Research, 1997.
- Study section member NIH-NIAID, Special Emphasis Panel: HIV pre-clinical/clinical vaccine, 1997.
- Dutch Cancer Society: Cancer Diagnosis Research Review Section 2000, 2004.
- The Cancer Research Campaign UK: Senior Clinical Research Fellowship Review, 2001.
- Study section member NIH, NCI, Special Emphasis Panel: Cancer Prognosis and Prediction 2001, 2002, 2004.
- Program Project Subcommittee C Review Group (*ad hoc*) NIH/NCI (Basic and Pre-Clinical), NIH, NCI (*ad hoc*); Site visits; 1998 (1), 1999 (1), 2000 (2), 2002 (1).
- Program Project Parent Subcommittee C Review Group (*ad hoc*) NIH/NCI (Basic and Pre-clinical) (*ad hoc*); 2000 (2), 2001 (1), 2002 (1).
- Program Project Parent Subcommittee C Review Group (*ad hoc*) NIH/NCI (Basic and Pre-Clinical), NIH, NCI, 2003-present, Permanent Member.
- Program Project Committee E Review NIH/NCI (*ad hoc*) (Cancer Prevention, Detection, Epidemiology), site visit 2002.
- Program Project Parent Subcommittee E Review Group (*ad hoc*) NIH/NCI (ad hoc)(Cancer Prevention, Detection, Epidemiology) (2002).
- The Cancer Research Campaign, UK. CRC Fellowship Program Review, 2001.
- NIH, NCI Spore (skin cancer) Committee 2001, 2003; Spore (GI and prostate cancer) Committee 2001; Spore (Breast) Committee 2002, 2005, 2006, 2007. Senior Member.
- NIH, NCI Study Section Special Emphasis Panel Loan Repayment NIH Committee, 2003.
- NIH, NCI Study Section Member Cancer Biomarkers, 2003-2006. Second term, 2007-present.
- NIH, NCI Resources to Advance Melanoma Research Committee, 2004.
- American Association Cancer Research Fellowship Awards Committee, 2003.
- NIH, NCI Study Section, Program Project Subcommittee C, Member 2003-present.
- NIH, NCI Study Section, Program Project Subcommittee D, (*ad hoc*) 2003.
- NIH, NCI, Study Section C, Chairman Study Review Cluster Program Project 2004.
- National Medical Research Council, Review Section, Singapore 2004.
- Research Grants Council, Hong Kong, China (2004, 2005).
- NIH, NCI, Study Section, Chairman, RFA CA 06-001, Circulating Cells and DNA in Cancer Detection, SBIR 2005.
- Centers of Cancer Nanotechnology Excellence, NCI, RFA, Special Emphasis Panel Member, 2005.
- Melanoma Research Program. Grant Review Panel. 2005.
- NCI, Cancer Center Review Group 2006.
- Cancer Genome Characterization Centers Review Committee, NCI, RFA, Special Emphasis Panel Member 2006.
- NCI-Avon Breast Review Committee, Special Emphasis Panel Member 2007.

- Adelson Medical Research Foundation (Melanoma) Executive Advisory Committee 2007.
- Breast Cancer Research Program CDRMP Clinical and Therapeutics Review 2008.
- Breast Cancer Research Program CDRMP Concept Awards Review 2009, 2010.
- NIH, SBIR/STTR, Small Business: Cancer Diagnostic and Therapeutics, 2010.
- Grant Review, Fondazione Cariplo, Milan, Italy, 2010.
- NCI, Drug Discovery, Biomarkers, and Therapeutics P01 Review Committee E, 2009-2010.

Peer-Reviewed Manuscripts

1. Balk SD, Mitchell RS, LeStourgeon D, **Hoon BS**. Thymidine and hypoxanthine requirements for the proliferation of normal and Rous sarcoma virus-infected chicken fibroblasts in the presence of methotrexate. Cancer Res. 39:1854-6, 1979.

2. Balk SD, Polimeni PI, **Hoon BS**, LeStourgeon DN, Mitchell RS. Proliferation of Rous sarcoma virus-infected, but not of normal, chicken fibroblasts in a medium of reduced calcium and magnesium concentration. Proc Natl Acad Sci U S A. 76:3913-6, 1979.

3. **Hoon BS**, Balk S, Mitchell RS, LeStourgeon D. Rapid, quantitative adipose conversion of chicken fibroblasts by high concentrations of chicken serum or plasma. Experientia. 35:1038-9, 1979.

4. Balk SD, **Hoon BS**, King GM, Loskutoff D, Mitchell RS, LeStourgeon DN, Weselake RJ. Rapid, reversible rounding and aggregation of Rous sarcoma virus-infected chicken fibroblasts induced by a plasma macromolecule. Cancer Res. 40:1753-60, 1980.

5. Ramshaw IA, Carlsen SA, **Hoon D**, Warrington RC. A 6-thioguanine-resistant variant of the 13762 cell line which is no longer tumorigenic or metastatic. Int J Cancer. 30(5):601-7, 1982.

6. **Hoon DB**, Ziola B, Carlsen S, Warrington R, Ramshaw I. Circulating immune complexes and immunoglobulin M-class rheumatoid factor in rats bearing mammary adenocarcinomas which vary in ability to metastasize. Cancer Res. 43(1):114-9, 1983.

7. **Hoon DB**, Ziola B, Ramshaw I. Circulating immune complexes in rats bearing 6-thioguanine-resistant variants of the 13762 mammary adenocarcinoma. Cancer Res. 44(6):2406-9, 1984.

8. **Hoon DB**, Wang HC, Ramshaw IA. Increased metastatic ability and bone formation of a mammary adenocarcinoma in vivo after in vitro passaging. Eur J Cancer Clin Oncol. 20:1517-26, 1984.

9. **Hoon DS**, Ramshaw IA. Chemoimmunotherapeutic effect of cyclophosphamide on the highly metastatic MAT 13762 tumor. Cancer Immunol Immunother. 20:175-8, 1985.

10. **Hoon DB**, Ng SK, Ramshaw IA. Analysis of mammary tumour cell metastasis and release of bound n-acetylneuraminic acid. Br J Cancer. 51:775-81, 1985.

11. **Hoon DS**, Wen DR, Stene M, Gupta RK, Cochran AJ. Inhibition of lymphocyte motility by interleukin 2. Clin Exp Immunol. 66:566-73, 1986.

12. Cagle LA, **Hoon DSB**, Cochran AJ, Morton DL. Immunocompetence of draining lymph nodes of breast cancer. Surg Forum 37: 376-379, 1986.

13. **Hoon DS**, Ramshaw IA. A 6-thioguanine-resistant variant of the rat mammary adenocarcinoma 13762 that is more immunogenic. Cancer Immunol Immunother. 24:42-8, 1987.

14. Cochran AJ, Pihl E, Wen DR, **Hoon DS**, Korn EL. Zoned immune suppression of lymph nodes draining malignant melanoma: histologic and immunohistologic studies. J Natl Cancer Inst. 78:399-405, 1987.

15. **Hoon DS**, Bowker RJ, Cochran AJ. Suppressor cell activity in melanoma-draining lymph nodes. Cancer Res. 47:1529-33, 1987.

16. **Hoon DS,** Korn EL, Cochran AJ. Variations in functional immunocompetence of individual tumor-draining lymph nodes in humans. Cancer Res. 47(6):1740-4, 1987.

17. Naeim F, **Hoon DS**, Cheng L, Herschman H, Cochran A Jr. Reactivity of neoplastic cells of hairy cell leukemia with antisera to S-100 protein. Am J Clin Pathol. 88:86-91, 1987.

18. Ando I, **Hoon DS**, Suzuki Y, Saxton RE, Golub SH, Irie RF. Ganglioside GM2 on the K562 cell line is recognized as a target structure by human natural killer cells. Int J Cancer. 40:12-7, 1987.

19. Ando I, **Hoon DB**, Pattengail PK, Golub SH, Irie RF. Ganglioside GM2 as a target structure recognized by human natural killer cells. J Clin Lab Anal. 1: 209-213, 1987.

20. McBride WH, **Hoon DB**, Jung T, Naungayan J, Nizze A, Morton DL. Cyclophosphamide-induced alterations in human monocyte functions. J Leukoc Biol. 42:659-66, 1987.

21. Ibayashi Y, **Hoon DS**, Golub SH. The regulatory effect of adherent cells on lymphokine activated killer cells. Cell Immunol. 110:365-78, 1987.

22. Niku SD, **Hoon DS**, Cochran AJ, Morton DL. Isolation of lymphocytes from clotted blood. J Immunol Methods. 105:9-14, 1987.

23. **Hoon DS**, Irie RF, Cochran AJ. Gangliosides from human melanoma immunomodulate response of T cells to interleukin-2. Cell Immunol. 111:410-9, 1988.

24. Hachida M, **Hoon DS**, Morton DL. A comparison of solutions for lung preservation using pulmonary alveolar type II cell viability. Ann Thorac Surg. 45:643-6, 1988.

25. Morton DL, Foshag LJ, Nizze JA, Gupta RK, Famatiga E, **Hoon DS**, Irie RF. Active specific immunotherapy in malignant melanoma. Semin Surg Oncol. 5:420-5, 1989.

26. Wen DR, **Hoon DS**, Chang C, Cochran AJ. Variations in lymphokine generation by individual lymph nodes draining human malignant tumors. Cancer Immunol Immunother. 30:277-82, 1989.

27. Klein JR, **Hoon DS**, Nangauyan J, Okun E, Cochran AJ. S-100 protein stimulates cellular proliferation. Cancer Immunol Immunother. 29:133-8, 1989.

28. **Hoon DS**, Jung T, Naungayan J, Cochran AJ, Morton DL, McBride WH. Modulation of human macrophage functions by gangliosides. Immunol Lett. 20:269-75, 1989.

29. **Hoon DS**, Ando I, Sviland G, Tsuchida T, Okun E, Morton DL, Irie RF. Ganglioside GM2 expression on human melanoma cells correlates with sensitivity to lymphokine-activated killer cells. Int J Cancer. 43:857-62, 1989.

30. Cochran AJ, Wen DR, Farzad Z, Stene MA, McBride W, Lana AM, **Hoon DS**, Morton DL. Immunosuppression by melanoma cells as a factor in the generation of metastatic disease. Anticancer Res. 9:859-64, 1989.

31. Yamamoto S, **Hoon DS**, Chandler P, Schmid I, Irie RF. Generation of lymphokine-activated killer cell activity by low-dose recombinant interleukin-2 and tumor cells. Cell Immunol. 128:516-27, 1990.

32. **Hoon DBS**, Bowker R, Cochran AJ. Suppressor cell activity human breast cancer draining lymph nodes. Surgical Res. Comm. 9:167-176, 1990.

33. **Hoon DS**, Foshag LJ, Nizze AS, Bohman R, Morton DL. Suppressor cell activity in a randomized trial of patients receiving active specific immunotherapy with melanoma cell vaccine and low dosages of cyclophosphamide. Cancer Res. 50:5358-64, 1990.

34. Yamamoto S, Yamamoto T, Saxton RE, **Hoon DS**, Irie RF. Anti-idiotype monoclonal antibody carrying the internal image of ganglioside GM3. J Natl Cancer Inst. 82:1757-60, 1990.

35. Economou JS, Hoban M, Lee JD, Essner R, Swisher S, McBride W, **Hoon DB**, Morton DL. Production of tumor necrosis factor alpha and interferon gamma in interleukin-2-treated melanoma patients: correlation with clinical toxicity. Cancer Immunol Immunother. 34:49-52, 1991.

36. **Hoon DS**, Banez M, Okun E, Morton DL, Irie RF. Modulation of human melanoma cells by interleukin-4 and in combination with gamma-interferon or alpha-tumor necrosis factor. Cancer Res. 51:2002-8, 1991.

37. **Hoon DS**, Okun E, Banez M, Irie RF, Morton DL. Interleukin 4 alone and with gamma-interferon or alpha-tumor necrosis factor inhibits cell growth and modulates cell surface antigens on human renal cell carcinomas. Cancer Res. 51:5687-93, 1991.

38. Shibata M, **Hoon D**, Okun E, Morton D. Modulation of histamine type II receptors on CD8+ T cells by interleukin-2 and cimetidine. Int Arch Allergy Immunol. 97:8-16, 1992.

39. Hayashi Y, **Hoon DS**, Park MS, Terasaki PI, Morton DL. Cytotoxic T cell lines recognize autologous and allogeneic melanomas with shared or cross-reactive HLA-A. Cancer Immunol Immunother. 34:419-23, 1992.

40. Hayashi Y, **Hoon DS**, Park MS, Terasaki PI, Foshag LJ, Morton DL. Induction of CD4+ cytotoxic T cells by sensitization with allogeneic melanomas bearing shared or cross-reactive HLA-A. Cell Immunol. 139:411-25, 1992.

41. **Hoon DS**, Kaback MM, Lim-Steele J, Tsuchida T, Morton DL, Irie RF. Ganglioside GM2 levels in human melanoma cells: inverse correlation with lysosomal beta-hexosaminidase A activity. Biochem Int. 27:343-52, 1992.

42. Morton DL, Foshag LJ, **Hoon DS**, Nizze JA, Famatiga E, Wanek LA, Chang C, Davtyan DG, Gupta RK, Elashoff R, Irie RF. Prolongation of survival in metastatic melanoma after active specific immunotherapy with a new polyvalent melanoma vaccine. Ann Surg. 216:463-82, 1992.

43. Morisaki T, Yuzuki DH, Lin RT, Foshag LJ, Morton DL, **Hoon DS**. Interleukin 4 receptor expression and growth inhibition of gastric carcinoma cells by interleukin 4. Cancer Res. 52:6059-65, 1992.

44. Takeyama H, **Hoon DS**, Saxton RE, Morton DL, Irie RF. Growth inhibition and modulation of cell markers of melanoma by S-allyl cysteine. Oncology. 50:63-9, 1993.

45. Uchiyama A, Hoon DS, Morisaki T, Kaneda Y, Yuzuki DH, Morton DL. Transfection of interleukin 2 gene into human melanoma cells augments cellular immune response. Cancer Res. 53:949-52, 1993.

46. Hayashi Y, **Hoon DS**, Foshag LJ, Park MS, Terasaki PI, Morton DL. A preclinical model to assess the antigenicity of an HLA-A2 melanoma cell vaccine. Cancer. 72:750-9, 1993.

47. **Hoon DS**, Morisaki T, Uchiyama A, Hayashi Y, Foshag LJ, Nizze AJ, Morton DL. Augmentation of T-cell response with a melanoma cell vaccine expressing specific HLA-A antigens. Ann N Y Acad Sci. 690:343-5, 1993.

48. **Hoon DS**, Wang Y, Sze L, Kanda H, Watanabe T, Morrison SL, Morton DL, Irie RF. Molecular cloning of a human monoclonal antibody reactive to ganglioside GM3 antigen on human cancers. Cancer Res. 53:5244-50, 1993.

49. **Hoon DS**, Hayashi Y, Morisaki T, Foshag LJ, Morton DL. Interleukin-4 plus tumor necrosis factor alpha augments the antigenicity of melanoma cells. Cancer Immunol Immunother. 37:378-84, 1993.

50. **Hoon DS**, Okun E, Neuwirth H, Morton DL, Irie RF. Aberrant expression of gangliosides in human renal cell carcinomas. J Urol. 150:2013-8, 1993.

51. Morisaki T, Uchiyama A, Yuzuki D, Essner R, Morton DL, **Hoon DS**. Interleukin 4 regulates G1 cell cycle progression in gastric carcinoma cells. Cancer Res. 54:1113-8, 1994.

52. Barth A, **Hoon DS**, Foshag LJ, Nizze JA, Famatiga E, Okun E, Morton DL. Polyvalent melanoma cell vaccine induces delayed-type hypersensitivity and in vitro cellular immune response. Cancer Res. 54:3342-5, 1994.

53. Morisaki T, Morton DL, Uchiyama A, Yuzuki D, Barth A, **Hoon DS**. Characterization and augmentation of CD4+ cytotoxic T cell lines against melanoma. Cancer Immunol Immunother. 39:172-8, 1994.

54. Morioka N, Kikumoto Y, **Hoon DS**, Morton DL, Irie RF. A decapeptide (Gln-Asp-Leu-Thr-Met-Lys-Tyr-Gln-Ile-Phe) from human melanoma is recognized by CTL in melanoma patients. J Immunol. 153:5650-8, 1994.

55. **Hoon DS**, Yuzuki D, Hayashida M, Morton DL. Melanoma patients immunized with melanoma cell vaccine induce antibody responses to recombinant MAGE-1 antigen. J Immunol. 154:730-7, 1995.

56. Morioka N, Kikumoto Y, **Hoon DS**, Morton DL, Irie RF. Cytotoxic T cell recognition of a human melanoma derived peptide with a carboxyl-terminal alanine-proline sequence. Mol Immunol. 32:573-81, 1995.

57. **Hoon DS**, Wang Y, Dale PS, Conrad AJ, Schmid P, Garrison D, Kuo C, Foshag LJ, Nizze AJ, Morton DL. Detection of occult melanoma cells in blood with a multiple-marker polymerase chain reaction assay. J Clin Oncol. 13:2109-16, 1995.

58. **Hoon DS**, Doi F, Giuliano AE, Schmid P, Conrad AJ. The detection of breast carcinoma micrometastases in axillary lymph nodes by means of reverse transcriptase-polymerase chain reaction. Cancer. 76:533-5, 1995.

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